

DETAILED ACTION

1. The examiner acknowledges receipt of request for extension of time, amendment and remarks, all filed 04/22/2011. Claims 28, 39 and 41 are amended. Claims 28, 30-32, 34, 39 and 41 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claim 39 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. Claim 39 has been amended to recite "nonionic triblock copolymers of (polyoxyethylene) and "polyoxypropylene) in place of the trade name PLURONIC. However, triblocks of (polyoxyethylene --- PEO) and (polyoxypropylene --- PPO) are either (PEO)(PPO)(PEO) or PEO-PPO-PEO having the polyoxpropylene flanked by two polyoxyethylene and which are the PLURONICs or (PPO)(PEO)(PPO) or PPO-PEO-PPO having polyoxyethylene flanked by two polyoxypropylene, which is reversed PLURONIC or PLUROIC-R (see paragraph [0023] of Bothe et al. US 20030209818 A1 and paragraph [0029] of Li et al. US 20020019369 A1).

5. It appears that the triblock copolymer of the invention is PLURONIC and it is suggested that the structure representing PLURONIC, which the PEO-PPO-PEO be claimed to avoid

introduction of new matter into the claims since PLURONIC-R was not envisioned at the time the application was filed.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 28, 30, 31, 32 and 39 are rejected under 35 U.S.C. 102(b) as being anticipated by Mori et al. (US 6,239,177 B1).

8. Mori discloses composition in the form of patch or film (column 5, lines 13 and 58-65), the composition comprises tranilast (see the whole document with emphasis on the abstract; column 2, line 40; column 3, lines 39-51), solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin (abstract; column 3, lines 55 to column 5, line 19), and water soluble polymers for adhesives, the polymers are selected from polyacrylic acid and acrylate copolymer, cellulose, gelatin, casein, polyvinyl alcohol, polyvinylpyrrolidone, polyethylene glycol, naturally occurring polysaccharide and can be used alone or in combination of two or more; fat soluble polymers can also be used as the adhesive (abstract; column 5, lines 20-47).

9. The tranilast meets the tranilast of claims 28, 31 and 32. Claims 31 and 32 are directed to the properties/characteristics of the composition.

10. The adhesive material such as the polyvinyl alcohol meets the requirements for biodegradable polymer of claim 28 and the polyvinyl alcohol of claim 30. When the adhesive material is a gum arabic or polysaccharide or gelatin, the biodegradable polymer of claim 39 is met.

11. The solubilizer, absorption aid and dispersant for enhancing the absorption of tranilast into the skin meet the limitation of the optional therapeutic agent of claim 28.

Response to Arguments

12. Applicant's arguments filed 04/22/2011 have been fully considered but they are not persuasive.

13. Applicant's arguments on pages 7-10 centers on applicant's contention that Mori's composition contains water, which is excluded by the consisting language and that the examiner's argument that the patch of Mori does not contain water is not found in Mori.

14. Response: The examiner disagrees that Mori does not teach the claimed composition as follows: A) The rejection under 35 USC 102(b) is a new rejection in the office action of 12/22/2010. The final rejection of 01/08/2010 does not have this rejection and the Appeal Brief filed 08/09/2010 did not present arguments against the rejection under 35 USC 102(b). It is therefore unclear how the examiner may have responded to applicant's argument that was not present. B) However, the presence of water in Mori meets the limitation of optional therapeutic agent and the presence of optional therapeutic agent does not exclude water. In fact water meets the limitation of optional therapeutic agent. Therefore, because claim 28 contains optional additional therapeutic agent, a composition containing water and/or other therapeutic agents meets that limitation. This is supported by the fact that the instant specification at paragraph

[0037] of the published application mentions additional therapeutic agent without defining or disclosing agents that would be additional therapeutic agents.

Claim Rejections - 35 USC § 103

15. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

16. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 28 and 30 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1).

18. Mori is described above as anticipating claim 28. Mori discloses that it has been known the effective concentration of tranilast on the skin tissue for treating keloid is about 8-10 $\mu\text{m/g}$. The %amount of tranilast in the composition of Mori is anticipated at 0.05 to 5 wt% of the composition.

19. Mori does not disclose the amount of tranilast in the composition in terms of mg/kg bodyweight recited in claim 34. However, taken the general teaching of Mori regarding use of tranilast to treat keloid or allergic dermatitis, one having ordinary skill in the art at the time the invention was made would be motivated to optimize the composition of Mori by using amounts of tranilast that would be effective in the treatment. In the absence of factual showing, amount of tranilast in the broad range of 0.01 mg/kg body weight to 3000 mg/kg bodyweight recited in claim 34 is not inventive over the teaching of Mori.

Response to Arguments

20. Applicant's arguments filed 04/22/2011 have been fully considered but they are not persuasive.

21. Applicant argues that the skilled artisan would have eliminated water in order to arrive at the claimed composition.

22. Response: The examiner disagrees with the applicant that elimination of water is required to arrive at the claimed composition because water meets the limitation of additional therapeutic agent and its elimination is not warranted.

23. Claims 28 and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mori et al. (US 6,239,177 B1) as evidenced by Isaji et al. ("Tranilast: A New Application in the Cardiovascular Field as An Antiproliferative Drug," in Cardiovascular Drug Reviews, Vol. 16, No. 3, pp. 288-299, provided by applicant on an IDS) in view of Pope et al. (US 5,948,822).

24. Mori has been described above to anticipate claim 28. Mori's composition contains tranilast which an antiproliferative agent according to Isaji. Mori contemplates treating keloid,

hypertrophic scar and allergic dermatitis by topically applying the composition containing tranilast (column 2, lines 61-67).

25. Mori does not have a second agent that is also an antiproliferative agent as required by claim 41. However, Pope discloses antiproliferative agent that reduces hyperproliferative keloid formation (column 3, lines 12-34; column 5, lines 1, 2, 6 and 7).

26. Therefore, given the general teachings of Mori and Pope, one having ordinary skill in the art at the time the invention was made would be motivated to add a second anti-proliferative agent to the tranilast containing composition of Mori with a reasonable expectation that the antiproliferative agent and tranilast would act in synergy for effectively treating hyperproliferative keloid formation.

Response to Arguments

27. Applicant's arguments filed 04/22/2010 have been fully considered but they are not persuasive.

28. Applicant states that the deficiencies of Mori described on pages 7-10 are applicable here and that Pope fails to cure the deficiencies because the skilled artisan would not have been motivated to eliminate water from Mori's composition to arrive at the claimed composition.

29. Response: The examiner disagrees. Pope was not used as a reference for providing motivation to eliminate water and the response provided in paragraph 14 above is also applicable here in response to the arguments presented on pages 7-10 of the remarks. However, it is not necessary to eliminate water to arrive at the claimed composition because water meets the limitation of additional therapeutic agent.

Double Patenting

30. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

31. Claims 28, 30-32 and 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of copending Application No. 10/780,452 (US 20050181023) in view of Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

32. The compositions of copending claims 14, 19, 21-23, 27, 28, 31, 34, 37, 39-41 of application number 10/780,452 contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening.

33. This is a provisional obviousness-type double patenting rejection.

34. Claims 28, 30-32 and 39-41 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of copending Application No. 12/021,546 (US 20080119494) in view of

Chandrasekar et al. ("Platelets and Restenosis," in Journal of the American College of Cardiology, Vo. 35, No. 2, 2000, pp 555-562) or Miyazawa et al. ("Effects of pemirolast and tranilast on intimal thickening after arterial injury in the rat," in Journal of Cardiovascular Pharmacology, Vol. 30, no. 2, Aug. 1997).

35. The method of copending claims 1-6, 11, 14-16, 19, 21-25, 27-34, 37, 40 and 41 of 10/780,452 uses compositions that contain Pemirolast instead of Tranilast. Both the Pemirolast and the tranilast have the functionality of inhibiting post-operative adhesion. It is however known in the art that both tranilast and pemirolast are antiallergic agents known to reduce intimal thickening as disclosed by Chandrasekar (first full paragraph, left column of page 559) and Miyazawa (abstract). Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use pemirolast in place of tranilast with the expectation that the composition would reduce intimal thickening. One having ordinary skill in the art would have been motivated to use tranilast or pemirolast to reduce intimal thickening with the expectation to either would reduce intimal thickening or post-operative adhesions.
36. This is a provisional obviousness-type double patenting rejection.

Response to Arguments

37. Applicant's arguments filed 04/22/1011 have been fully considered but they are not persuasive.
38. Applicant requests that the provisional double patenting rejection be held in abeyance until "notification of allowable subject matter."
39. Response: The provisional obviousness double patenting rejection is not the only rejection in the examined application and the rejection will continue to be made until the

rejection is overcome as stated in MPEP 804 [R-5], I B, that "the "provisional" double patenting rejection should continue to be made by the examiner in each application as long as there are conflicting claims in more than one application unless that "provisional" double patenting rejection is the only rejection remaining in at least one of the applications." As noted above, the provisional obviousness double patenting rejection is not the only rejection remaining in this examined application. Thus rejection is maintained and is not held in abeyance.

40. No claim is allowed.

41. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

42. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

43. Any inquiry concerning this communication or earlier communications from the examiner should be directed to BLESSING FUBARA whose telephone number is (571)272-0594. The examiner can normally be reached on Monday to Thursday from 7 a.m. to 5:30 p.m.

44. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Y. Kwon can be reached on (571) 272-0581. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

45. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Blessing M. Fubara/
Primary Examiner, Art Unit 1613